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EuropaBio 1998
The European Biotechnology Congress

Organized by EuropaBio representing the Bio-industries in partnership with Flanders Institute for Biotechnology (VIB), Flanders Foreign Investment Office (FFIO), Nature Biotechnology at the Brussels Congress Centre, October 27 - 30, 1998.

Major sponsor: Flanders Foreign Investment Office
Organizing Committee members: Monsanto Europe, Novartis International, Pioneer, DGXII- European Commission, Nestle, Flanders Inter-university Institute for Biotechnology, SmithKline Beecham Biologicals, Genzyme

Introduction

The second *EuropaBio '98 European Biotechnology Congress* was attended by about 650 delegates from a wide range of organizations, food and bio-industry, member states' Governments, European Union representatives, researchers and Farmers Organizations. Last year it was held in Amsterdam. Next year it will be held in Germany. Representatives were from Australia, Austria, Belgium, Brazil, Canada, Cuba, Denmark, Egypt, Finland, France, Germany, Hong Kong, Hungary, Israel, Italy, Japan, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, United States of America, and the United Kingdom.

The main theme of the four-day business conference was to assess the competitiveness of the European biotechnology industry in relation to competitor markets, in particular the United States, and finding solutions for improving Europe's business environment.

The conference covered six main topics which were held in parallel sessions: Business Development and Marketing, Finance, Bio Ethics, Technology Transfer, Regional Cluster Development, Talking to consumers, Regulation and Science and Technology.

The writer followed keynote addresses and the sessions on Regulation, Talking to Consumers mixed with some Technology Transfer. Here follow some highlights.

General

Biotech research institutes and businesses are flourishing in Europe. The main issues to be addressed in the EU are those of improving legislation, and increasing information flows to consumers. Several main speakers called for a dialogue with consumer organizations in order to educate them about the benefits of biotechnology.

Differences between the U.S. and the EU

Hugh Grant of Monsanto USA mentioned in his keynote address, that biotechnology is a revolutionary science and that it must be further developed in order to feed the world, increase human health through better functional foods, and create employment opportunities. According to Grant, the main difference between the U.S. and the EU in accepting biotech innovations is that U.S. consumers have faith in the U.S. regulatory and product approval system while in the EU consumers distrust science because of the occurrence of diseases such as BSE and Swine fever. EU consumers also distrust multinational companies and often wonder what the environmental side effects of biotech are. Grant also stated that "food is celebrated" in the EU and that food is part of member states' national cultures. He urged for a harmonized, U.S. - EU approval system of GMO products. He added that Monsanto now supports labeling "as it makes sense".

Other speakers mentioned that the U.S. approval system (FDA, EPA,USDA) is clear and transparent and based on sound science. According to Anja Matzk of *Kleinwanzlebener Saatzucht AG,* the Unites States' GMO approval system could function as an example for Europe. It takes an average of one year in the U.S. to approve a GMO corn variety while in the EU it takes 3 years to infinity.
The main advantages of the U.S. system is that approvals are done on a federal level, are product based, adapted to pre-existing legislation and integrated in the existing structures of USDA/FDA/EPA. No speaker was identified who stated that EU legislation functions well. The main problems with the EU are that a complete new legislation was designed for the approvals of GMO's and that this system is process based rather than product based, and that one approval involves 15 member states who do not speak a common language and have different interests.

Regulations: The Bad News

According to the speakers on regulation one main problem relates to the fact that an EU Directive is not necessarily binding and allows member states a certain degree of freedom. This means that national Parliaments can decide how and when to implement a EU Directive. As one speaker noted " Although all member states have implemented the Directive 90/220/EEC, the execution of these rules differ". This leads to differences amongst member states in pursuing the regulatory procedures and leads to chaos and trade losses.

The Biotech Industry considers the EU regulatory process as extremely murky and cumbersome. Lack of decision making by EU regulators contributes to public uncertainty about GMO food products according to the industry representatives. The EU legislators, on the other hand, believe that the EU regulatory process is a result of the low acceptance of GMO food products by the public.

The legal Framework in Europe is that of Directive 90/220/EEC (deliberate release into the environment

of genetically modified organisms) and of Directive 90/219/EEC (contained use of GMP). The main conclusions are:

- EU member states do not agree with one and another. Lengthy debates are held without result. There is thus an urgent need to establish in the EU a clear regulatory framework for the approval of GMO products.
- S The new and forthcoming amendments to these Directives will not improve the approval process in the EU but it will make it worse and even more cumbersome. One of the problems is that nobody knows exactly what the regulations are as these are open to different interpretations and national member state manipulations. It is obvious that EU regulations are only designed to restrict trade and protect the EU market. One clear reason for this is that the EU lax two to five years behind in biotechnological innovations as compared to the U.S. and wants to come along side.
- S Most delegates agreed that only a clear and transparent and science-based regulatory framework will enhance human safety. Such legislation must be compatible with international legislation.

Good News

- S The pharmaceutical industry is positive about the clear EU regulation with regard to the approval of GMP (genetically modified products). This is clearly better organized as for the agribusiness industries and proves that it is possible to design transparent legislation.
- S Contrary to the EU legislation, the *Transatlantic Business Dialogue* on Food Biotechnology and the *Transatlantic Economic Partnership* were considered positive developments because much is at stake and the challenges are great just like the opportunities. The signing of the *Convention on Biological Diversity* is scheduled to be held in Cartagena, Columbia in February 1999.

Other

Several speakers (Nestle, AgrEvo, Monsanto) mentioned that in order to successfully market biotech products the industry must:
- pro-actively educate EU consumers
- work with Governments and NGO's with regard to wide biotech acceptance
- actively pursue harmonization to achieve transparent legislation
- What we have seen in Biotech is just the beginning. Technological developments move with an incredible speed especially in the fields of vaccinations, prions research, cloning and bio-informatics.
- Soon, the full mapping of plant, animal and human genome will be realized. This will enable targeted replacements of genes with alternatives from another organism.
- in 1997 about 20 million hectares were planted with GMO crops outside Europe, while in Europe 0 hectares were planted in 1997. Therefore the final speaker asked ***" What's going on?"***